Medical Assessments, Inc.

4833 Thistledown Dr.

Fort Worth, TX 76137

P: 817-751-0545

F: 817-632-9684

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IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
KCI Wound VAC Kit Hyperbaric Treatment x 6 months Wound care x 6 months

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
The Reviewer is a Board Certified Orthopaedic Surgeon with over 13 years of experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:
The claimant is a male who was injured when he fell 15 feet from a x on xx/xx/xx. Current diagnoses include injury of the lower extremity, osteomyelitis, and pain in the lower limb.

Office visit. Claimant reported ankle and foot pain, left side. **Current medications:** Amlodipine 5mg, Diovan 320mg, Metoprolol 50mg, Janumet 50mg, Lisinopril Hydrochlorothiazide 20mg, Hydrocodone 10mg, Metformin 500mg.

Office visit. Claimant reported ankle and foot pain left side, draining, increase pain. He is taking more pain meds.

New patient visit. **Current Medications: Lisinopril, Metoprolol, Metformin. Assessment:** Left distal tibia fracture malunion with traumatic ostcarthritis of the ankle joint. **Plan:** the patient is going to need ankle fusion to obtain relief. However, he may need further debridement of the injection in the distal tibia and ankle area with antibiotics to clear this up before he can have further ankle fusion and surgery.

Office visit. Claimant has been wearing boot more and he thinks it has helped the wound close again. Has limited ankle movement.

Office visit. Claimant's symptoms are improved since last visit, less injection. No further purulent discharge, has lots of soreness/pain and took more pain meds for it a few weeks ago. Claimant wants 2nd opinion on possible ankle replacement surgery.

MRI left ankle. **Impression:** 1. significant post traumatic/infectious changes are present involving the ankle and posterior subtalar joints. If active infection is suspected, MRI with and without contrast might be most useful study as 3 phase bone scan would likely be hot on all 3 phases regardless.

Office visit. Claimant reported ankle and foot pain, left side. He had surgery.

Follow up visit. Claimant was seen for wound check regarding left ankle. **Assessment:** Healing left ankle postoperatively.

Office visit. Claimant reported pain with ankle and foot. The wound is healing faster on the outside than inside. Claimant is doing his own wound care.

Office visit. Claimant present with ankle swelling, foot swelling and left side soreness. **Exam: Decreased ROM in left ankle.**

Operative report. **Postoperative Diagnosis:** Osteomyelitis of left distal and ankle joint.

Encounter Summary. Claimant reported left aching pain. Severe. Has been working and taking oxycodone 2-3 every 2-3 hours. Debridement of wound and antibiotic beads put in. Ankle and foot has swelling and deformity.

Encounter Summary. Claimant reported he was able to take some time off of work and has been taking less pain meds. He down to 6 per day.

Encounter Summary. Osteomyelitis is improving. **PE:** Irregular gait. **Assessment:** Patient is improving. Will adjust pain meds to wean down a bit.

06: Encounter and procedures. Patient reported worsening. He was hospitalized for leg wound opening up again and was on IV piperacillin and clindamycin. Wound is still draining. Pain has increased. Patient reported arthralgia's/joint pain. Left anterior ankle-open wound, edges are red, warm, swollen, yellow discharge, wound culture taken.

Office visit. Claimant presents with foot swelling. Area on leg has opened again, some drainage.

Encounter Summary. Patient's diabetes is severely uncontrolled and is back on insulin. He was advised to go to the ER. His sugars was >400. He was unable to do further labs due to insurance issues.

UR**.** Rationale for denial: The patient is a male who was injured when he fell from a x on xx/xx/xx**.** Current diagnoses include injury of the lower extremity, osteomyelitis, and pain in the lower limb. Treatments to date include walking boot, surgery, PT, hyperbaric treatment and medications. Medical history pertinent for hypertension and diabetes mellitus. He underwent ORIF of the left tibia on with subsequent removal of fixation hardware on. A 3 phase nuclear medicine bone study of the ankle was done review . This revealed marked increased activity in the distal left tibia in all three phases, consistent with osteomyelitis. The left ankle MRI on documented tibiotalar arthropathy with marked erosions and remodeling moderately suspicious for a chronic septic joint, particularly if it has been partially treated. The findings were also moderately suspicious for juxta cortical osteomyelitis extending up to 3 cm into the distal tibia osteomyelitis with arthrotomy of the ankle on. Upon consult, the patient reported worsening left ankle. There was swelling noted near the open wound area. A week ago, he "cut into it, releasing a great amount of pus." Augmentin was started. It was reported to be "better" but still very painful. Medications include amlodipine, cyclobenzaprine, eszopiclone, kydrocodone, Lantus Solostar, linezolid, Lisinopril, metformin, promethazine, and tramadol. There was 50% pain relief with current medications regimine. Examination of the left ankle revealed a "large wound with small open area" a healing incision was noted. For the requested wound care, the patient presented with a large wound on the left ankle with a small open area. He is a known diabetic with a known history of ostcomyclitis. Given that the area was still pinkish and diffusely swollen, wound care is reasonable. However, continued treatment with would care

must be supported by an interval evaluation. Thus, the medical necessary of the requested wound care for 6 months is not established.

UR. The patient is male who was injured when he fell xxxx from a x on xx/xx/xx. Current diagnoses include injury of the lower extremity, osteomyelitis and pain in the lower limb. While daily wound care and wound VAC kits are considered, continue treatment will be based on the objective functional response from the initial sessions. Also, the requested number of hyperbaric treatment sessions exceeds guideline recommendations. As per guideline, wounds must be evaluated at least every week during the administration of HBOT. Continue is not considered medically necessary if measurable signs of healing have not been demonstrated within any one-week period of treatment. Also, maximum treatment is for weeks or 20 visits. In agreement with the previous determination, the medial necessity of the request have not been established.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The request for KCI Wound VAC Kit Hyperbaric Treatment x 6 months is upheld.

The Official Disability Guidelines (ODG) supports negative pressure wound therapy in the treatment of diabetic ulcers. Wound healing is accelerated with this type of treatment in these patients.

is dealing with a draining wound in his leg associated with osteomyelitis. Once the patient's blood glucose is better controlled, he may benefit from a wound VAC. The wound VAC treatment should be monitored on a regular basis to determine whether this treatment is accelerating wound healing. Without interval assessments, six months of treatment is not medically necessary. Therefore, the request for KCI Wound VAC Kit Hyperbaric Treatment x 6 months Wound care x 6 months is non-certified.

ODG Guidelines:
Recommend the following combinations: for chronic wounds, (1) debridement stage, hydrogels; (2) granulation stage, foam and low-adherence dressings; and (3) epithelialization stage, hydrocolloid and low-adherence dressings; and for the epithelialization stage of acute wounds, low-adherence dressings. For more information, see the Forearm Wrist & Hand Chapter. Negative pressure wound therapy using a vacuum system is effective for soft tissue injuries around the foot and ankle. Negative pressure wound therapy can be used to cover exposed bone or soft tissue defects without frequent dressing changes, and reduces chronic edema and increases local blood supply, which enhances the formation of healthy granulation tissue. (Lee, 2009) See also Hyperbaric oxygen therapy. And see the Diabetes Chapter, Wound care (diabetic foot ulcers) & Collagenase ointment (wound healing).

Recommended in the treatment of diabetes-associated chronic leg wounds and diabetic ulcers of the feet. Under study for other wounds. Chronic skin wounds (including pressure ulcers, diabetic ulcers, and vascular ulcers) are a major source of morbidity, lead to considerable disability, and are associated with increased mortality. Vacuum-assisted closure therapy is a technology designed to improve wound healing. A thorough systematic review found consistent evidence of the benefit of negative pressure wound therapy (NPWT) in the treatment of diabetic ulcers of the feet. Results for bedsores was conflicting and research on mixed wounds was of poor quality, but promising. The review did not find evidence of increased significant complications. The review concluded that there is now sufficient evidence to show that NPWT is safe, and will accelerate healing, to justify its use in the treatment of diabetes-associated chronic leg wounds. There is also evidence, though of poor quality, to suggest that healing of other wounds may also be accelerated. (Xie, 2010) See also the Knee Chapter, where it is recommended, and the Shoulder Chapter, where it is Under study.

Recommended as an option for diabetic skin ulcers. The routine use of hyperbaric oxygen therapy (HBOT) is not justified for any type of wound. In people with foot ulcers due to diabetes, HBOT significantly reduced the risk of major amputation and may improve the chance of healing at 1 year. The application of HBOT to these patients may be justified where HBOT facilities are available, however economic evaluations should be undertaken. Hyperbaric oxygen therapy may improve oxygen supply to wounds and therefore improve their healing. Pooled data showed a reduction

in the risk (RR) of major amputation of 0.31 when adjunctive HBOT was used, compared to the alternative therapy. This analysis predicts that we would need to treat 4 individuals (NNT) with HBOT in order to prevent 1 amputation in the short term. HBOT may also be used in post-traumatic crush injury following open fracture, in compromised skin grafts, or in the re-implantation of traumatically amputated limb segment. In every case, the measurement of transcutaneous oxygen pressure is recommended as an index for the definition of the indication and of the evolution of treatment. (Kranke-*Cochrane*, 2004) (Berendt, 2006) Also see the Diabetes Chapter.

Recommend add-on therapy with growth factors and active skin substitutes as an option for treating uncomplicated diabetic foot ulcers. Treatment with becaplermin, rhEGF, and the metabolically active skin grafts Dermagraft and Apligraf, compared with standard wound care, resulted in a higher incidence of complete wound closure and shorter time to complete wound healing with statistically significant differences. (Buchberger, 2011) See Amniotic membrane allograft, where EpiFix® is recommended. See also Foot problems; & Hyperbaric oxygen therapy (HBOT) for diabetic skin ulcers. See also Wound dressings in the Forearm, Wrist, & Hand Chapter. See also Collagenase ointment (wound healing); Leech therapy; Maggot debridement therapy (wound healing).
Dermagraft is indicated for use in the treatment of full-thickness diabetic foot ulcers greater than six weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure. Dermagraft should be used in conjunction with standard wound care regimens and in patients that have adequate blood supply to the involved foot. (FDA, 2011)
For a complete list of Wound care topics addressed in multiple chapters, with hyperlinks, see the Burns Chapter.

Criteria for the use of Hyperbaric oxygen therapy (HBOT) --
Diabetic wounds of the lower extremities, specifically non-healing infected deep ulcerations (reaching tendons or bone) of the lower extremity in diabetic adults unresponsive to at least one month of meticulous wound care, in patients who meet the following criteria:
(1) Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
(2) Wounds must be Wagner Grade III (deep wound with abscess, osteomyelitis or tendonitis extending to those structures), Wagner Grade IV (gangrenous toes and forefoot) or V (gangrenous foot). Note: *HBOT is not considered medically necessary for superficial lesions*;
(3) Patient has failed an adequate course of standard wound therapy. The use of HBOT therapy is recommended as adjunctive therapy only after there are no measurable signs of healing for at least thirty consecutive days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in persons with diabetic ulcers should include:
(i) assessment of vascular status and correction of any vascular problems,
(ii) optimization of nutritional status,
(iii) optimization of glucose control,
(iv) debridement by any means to remove devitalized tissue,
(v) maintenance of clean, moist bed of granulation tissue with appropriated moist dressings,
(vi) appropriate off-loading,
(vii) necessary treatment to resolve any infection that might be present.
(4) Outpatient HBO treatments usually last 90 minutes to 2 hours, and patients typically undergo five daily treatments within a week.
(5) Wounds must be evaluated at least every week during the administration of HBOT. Continued treatment with HBOT is not considered medically necessary if measurable signs of healing have not been demonstrated within any one-week period of treatment.
(6) Maximum of four weeks, or 20 visits.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**